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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,033	05/25/2001	Ellen R. Bolte	6917 P 002	4271

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EXAMINER	
KAM, CHIH MIN	
ART UNIT	PAPER NUMBER
1653	6

DATE MAILED: 10/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/866,033	BOLTE, ELLEN R.	
	Examin r	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) *15-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2* .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-14, pervasive development disorder as the mental disorder and nitroimidazole as the antimicrobial composition in Paper No. 4 is acknowledged. The traversal is on the ground(s) that the search can be made without burden to include Group II since the two groups have some common classification and will share many common prior art references. This is not found persuasive because the traversal is not on the grounds that the inventions are not independent and distinct, rather, the traversal is on the grounds that there is no serious burden of search. As such restriction is proper if two or more claimed inventions are either independent **or** distinct. See MPEP 803. Furthermore, coexamination of additional group would require search of classes unnecessary for the examination of the elected claims (claims 1-14). For example, if Group II were included, it would require additional search of class 424, subclass 93.3. The restriction groups have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the invention is not coextensive particularly with regard to the literature search. A reference which would anticipate the invention of one group would not necessarily anticipate or make obvious any of the other group. Moreover, as to the question of burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not co-extensive and is much more important in evaluating the burden of search. Burden in examining materially different groups having materially different issues also exist. Therefore, coexamination of additional inventions would require a serious additional burden of search.

Regarding the requirement for selection of one mental disorder, applicants' argument is persuasive, upon reconsideration, the requirement is withdrawn. Regarding the requirement for selection of one antimicrobial composition, the argument is not persuasive because each type of antimicrobial composition which has different chemical property, inhibits microbes via different mechanism, and produces different effect in the method of treatment, is considered patentably distinct. Therefore, claims 1-14, all mental disorders cited in claim 2 or 9, and nitroimidazole (e.g., metronidazole) as the antimicrobial composition are examined.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 1-14 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating an individual exhibiting symptoms of autistic disorder or atypical psychosis, the method comprises administering to the individual metronidazole as an antimicrobial composition to inhibit or eliminate the symptoms of the disorder; and of treating an individual exhibiting symptoms of atypical psychosis, comprising administering to the individual metronidazole as indicated by the prior art, does not reasonably provide enablement a method for treating an individual exhibiting a symptom of a mental disorder, comprising administering to the individual an antimicrobial composition to inhibit or eliminate a symptom of the disorder; and a kit for treating an individual exhibiting a symptom of a mental disorder, comprising an antimicrobial composition in an amount effective to inhibit or

eliminate a symptom of the disorder. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 1-14 encompass a method for treating an individual exhibiting a symptom of a mental disorder, comprising administering to the individual an antimicrobial composition to inhibit or eliminate a symptom of the disorder (claims 1-7); and a kit comprising an antimicrobial composition in an amount effective to inhibit or eliminate a symptom of the disorder (claims 8-14). The specification, however, only discloses cursory conclusions (pages 3-5) without data supporting the findings, which state that administration of broad-spectrum antimicrobials has a profound effect on the normal gastrointestinal flora and can result in colonization of antimicrobial-resistant organisms such as *Clostridium difficile*, which would produce neurotoxins that mediate neurological disruption, and the present invention provides an antibacterial therapy directed to inhibit or eliminate these proliferating species to improve mental function. There are no indicia that the present application enables the full scope in view of treating symptoms of a mental disorder using an antimicrobial composition as discussed in the stated rejection. The present application provides no indicia and no teaching/guidance as to how the full scope of the claims is enabled. The factors considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F2d at 731,737, 8 USPQ2d at 1400,1404 (Fed. Cir.1988)). The factors most relevant to this rejection are the breath of the claims, the presence of working examples, the state of the prior art and relative skill of those in the art, the unpredictability of the art, the nature of the art, the amount of direction or guidance presented, and the amount of experimentation necessary.

(1). The breath of the claims:

The breath of the claims is broad and encompasses unspecified variants regarding various mental disorders and antimicrobial compositions, which are not adequately described or demonstrated in the specification.

(2). The presence or absence of working examples:

The specification demonstrates the treatment of children with autistic disorder, atypical psychosis or attention deficit/hyperactivity using vancomycin, metronidazole or clarithromycin (Examples 1-7). There are no other working examples indicating the claimed methods in association with various mental disorders using different antimicrobial compositions.

(3). The state of the prior art and relative skill of those in the art:

The prior art (Sandler et al., CID 30, 213-214 (January 2000)) indicates administration of metronidazole to a child having atypical psychosis improves the psychiatric condition of the patient during the treatment, however, the general knowledge and level of the skill in the art do not supplement the omitted description, the specification needs to provide specific guidance on the treating conditions such as the dose and the time for various mental disorders using various antimicrobial compositions to be considered enabling for variants.

(4). The amount of direction or guidance presented and the quantity of experimentation necessary:

The claims are directed to a method for treating an individual exhibiting a symptom of a mental disorder, comprising administering to the individual an antimicrobial composition to inhibit or eliminate a symptom of the disorder; and a kit comprising an antimicrobial composition in an amount effective to inhibit or eliminate a symptom of the disorder. The

specification indicates an antimicrobial, which has certain properties, is selected for antimicrobial therapy in treating mental disorders with a gut flora etiology (page 5, line 20-page 6, line 15) and further demonstrates the treatment of children with autistic disorder, atypical psychosis or attention deficit/hyperactivity using vancomycin, metronidazole or clarithromycin (Examples 1-7). However, the specification fails to provide the treating conditions such as the dose and the time for a different mental disorder using a different class of antibiotics, nor the effect of the treatment, the specification also fails to demonstrate the making and use of a kit comprising an antimicrobial composition. From the examples of treatment (Examples 1-7), it is not apparent how an individual with a different mental disorder is being treated using different classes of antibiotics and what effects the antimicrobial composition would produce. Moreover, there are no working examples indicating the use and the effect of a different class of antibiotic in treating a different mental disorder, and the preparation of a kit containing an antimicrobial composition. Since the specification fails to provide sufficient guidance on treating conditions on various mental disorders using various antimicrobial compositions, and the preparation of a kit, it is necessary to have additional guidance and to carry out further experimentation to assess the effects of these antibiotics.

(5). Predictability or unpredictability of the art:

The claim encompasses treating various mental disorders using various antimicrobial compositions. Since the treating conditions for various mental disorders using various antimicrobial compositions are not sufficiently described, the outcome of the claimed invention is highly unpredictable.

(6). Nature of the Invention

The scope of the claim includes treating various mental disorders using various antimicrobial compositions, however the specification has not demonstrated the treatment of various mental disorders using various antimicrobial compositions. Thus, the disclosure is not enabling for reasons discussed above.

In summary, the scope of the claim is broad, while the working example does not demonstrate the claimed variants, and the guidance and the teaching in the specification is limited, therefore, it is necessary to have additional guidance and to carry out further experimentation to assess the effects of various antimicrobials in treating metal disorders.

3. Claims 8-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 8-14 are directed to a kit for treating an individual exhibiting at least one symptom of a mental disorder, comprising an antimicrobial composition in an amount effective to inhibit or eliminate the symptom of the disorder. The specification indicates that a method of treating an individual exhibiting at least one symptom of a mental disorder, the method comprises administering to the individual an antimicrobial composition in an amount effective to inhibit or eliminate a symptom of the disorder (pages 3-5). However, the specification does not indicate a kit comprising an antimicrobial composition in an amount effective to inhibit or eliminate a symptom of the disorder. There is no disclosure regarding the preparation of the kit. Without guidance on the preparation of the kit, one skilled in the art would not know how to make and use of the kit. The lack of description on the making and use of the kit as

encompassed by the claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise terms that a skilled artisan would not recognize applicants were in possession of the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 3-8 and 10-14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 3-8 and 10-14 are indefinite because of the use of the term "one mental disorder" and "an antimicrobial composition". The term "one mental disorder" renders the claim indefinite, it is not clear which mental disorder is to be treated and which antimicrobial composition is used. Claims 3-7 and 9-14 are included in the rejection because they are dependent on rejected claims and do not correct the deficiency of the claim from which they depend.

5. Claims 3, 4, 10 and 11 are indefinite because the claim contains non-elected inventions.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 8-12 and 14 are rejected under 35 U.S.C. 102(b) as anticipated by the Web site of UWHC Antimicrobial Use Guide, Eighth Edition, July 1995-June 1996.

The guide teaches metronidazole has been manufactured as a drug (claims 8-11) for treatment of the bacterial infection by oral (claim 12) or IV route (claim 14). The drug containing an effective amount of metronidazole has inherent property of inhibiting or eliminating a symptom of the mental disorder.

7. Claim 13 is rejected under 35 U.S.C. 102(b) as anticipated by the Web site of INCHEM.

The Web site of INCHEM teaches metronidazole has been manufactured as a suppository for treatment of the anaerobic infections by rectal administration (claim 13). The drug containing an effective amount of metronidazole has inherent property of inhibiting or eliminating a symptom of the mental disorder.

8. Claims 1-5 are rejected under 35 U.S.C. 102(a) as anticipated by Sandler *et al.* (CID, 30, 213-214 (January 2000)).

Sandler *et al.* disclose a 14-year boy with Crohn's disease, who also developed atypical psychosis, was treated with metronidazole (250 mg t.i.d.), prednisone and mesalamine, within two weeks, both his GI and psychiatric symptoms dramatically abated (pages 213-214; claims 1-4). Subsequent deterioration in behavior was first noted 2 months after metronidazole treatment was discontinued, and 3 months after the psychiatric relapse, a second 1 month course of metronidazole (500 mg t.i.d. orally for 30 days) was initiated (page 214, claim 5). Within 3 weeks, a dramatic improvement in his psychiatric condition was noted, and by 5 weeks, he was essentially normal and not receiving any antipsychiatric medication.

Conclusions

9. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. CMK
Patent Examiner

Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER

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October 13, 2002